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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/798,380	03/12/2004	Viia Valge-Archer	08702.0137-00000	6499

22852 7590 07/11/2006

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EXAMINER	
STOICA, ELLY GERALD	
ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 07/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/798,380	VALGE-ARCHER ET AL.	
	Examiner	Art Unit	
	Elly-Gerald Stoica	1467	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-38* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-38* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

   I. Claims 1-13,15, 23 and 38, drawn to an isolated antibody that binds to IL-21 receptor, classified in class 530, subclass 388.22, for example.

   II. Claims 14, 16-22, 24 drawn to an isolated DNA sequence encoding an antibody, classified in class 435, subclass 320.1, for example.

   III. Claims 25-28, drawn to a method of regulating an immune response, classified in class 424, subclass 158.1, for example.

   IV. Claims 29-33, drawn to a method of treating and preventing an immune cell-associated disorder, classified in class 424, subclass 158.1 for example.

   V. Claims 34-36, drawn to a method of treating a hyperproliferative disorder, classified in class 424, subclass 158.1 for example.

2. Inventions I and II are directed to related distinct products, such as a nucleic acid sequence and a protein coded by that sequence. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the related

inventions do not overlap in scope because the antibody of Invention I and the nucleic acid sequence of Invention II are different products having different structures and different functions. For example, an antibody is an immunoglobulin that comprises a polypeptide, which has an antigen-binding site, while a deoxyribonucleic acid sequence is a polynucleotide stretch that codes for a polyribonucleotide chain. The antibody and the nucleic acid sequence also have distinct physical, chemical and functional properties requiring separate searches of the prior art. Moreover, the antibody is not an obvious variant of the nucleic acid sequence or vice versa by virtue of their entirely different structures and functions noted above. Thus by virtue of the different structures and functions of the inventions in Inventions I and II, these related inventions are related.

Because these inventions are independent or distinct for the reasons given above and Invention I and Invention II require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper. Invention I and Invention II are not identically classified under U.S. Patent Classification guidelines, thus, to search together would represent a search burden on the Examiner. Moreover, the searches in non-patent literature databases are extensive and do not overlap thus presenting a search burden on the Examiner if searched together. Because these inventions in Invention I and Invention II have acquired a separate status in the art in view of their different classification, restriction for examination purposes as indicated is proper.

Inventions I and each of the inventions III-V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the antibody of Invention I can be used in a materially different process of using this product such as for purification of the protein to which the antibody binds. Because these inventions are independent or distinct for the reasons given above and the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

Inventions II and each of the inventions III-V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the nucleic acid sequence of Invention II cannot be used *per se* for a method of regulating an immune response. Moreover, each of the methods of regulating an immune response of Inventions III-V are totally different than a method of use of the nucleic acid sequence of Invention II. Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Inventions III, IV and V are directed to related use of the anti IL-21 receptor antibody. The related inventions are distinct if the inventions as claimed do not overlap

in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the method of regulating an immune response of Invention III is distinct from the method of prevention and treatment of an immune cell associated disease of Invention IV as well as from the method of treating a hyperproliferative disorder of Invention V. For example, within the methods of regulating an immune response, a crucial aspect is constituted by disruption of antibody receptor binding which may have a myriad of effects upon signaling pathways, inducement or repression of key proteins that determine the proliferation, differentiation, cytokine secretion or survival of the immune cells (see p. 18, 2nd paragraph down to p15, line11 of the specification). Besides, the literature search required for each particular immune cells to be considered adds to the huge body of literature (patent and non-patent) considered for treating Invention II on the merits. The search for previous art needed for Invention IV encompasses an exhaustive effort of considering animal and human pathology and specific diseases (p. 11, lines 3-18 and p.46, 3rd paragraph down to p49, line 11 of the specifications). Moreover, while considering the methods of Invention IV, the Examiner has to analyze their pharmacological, toxicological and pharmacodynamic aspects, which again will add a considerable burden. As for the methods of Invention V, the hyperproliferative disorder search would lead to considering the extensive body of literature that covers neoplasia (p.49, line 12 down to p. 50, line 7 of the specification). If combined with the search comprising tumor biology assays employed for detection of

the proliferative modulatory effects of the antibodies claimed and the pharmaceutical compositions an modes of administration presented (p. 60, line 4 down to p. 63, line 3 of the specification) the volume of work is burdensome for this Invention, let alone the search for Inventions III and IV. Because these inventions are independent or distinct for the reasons given above and the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

Election of species

Regardless of which invention is elected, an election of species is required.

3. This application contains claims in Invention I directed to the following patentably distinct species: (Seq ID 1-3), (Seq ID 19-21), (Seq ID 47-49), (Seq ID 65-67), (Seq ID 83-85), (Seq ID 101-103), (Seq ID 119-121), (Seq ID 137-139). The species are independent or distinct because any species selected from above represent a distinct antibody. The application also contains in claims (4 and 5) the following patentably distinct species: (Seq ID 4-9), (Seq ID 22-26), (Seq ID 50-55), (Seq ID 68-73), (Seq ID 86-91), (Seq ID 104-109), (Seq ID 122-127), (Seq ID 140-145). The species are independent or distinct because any species selected from above may be part of a distinct antibody, and each set of sequences requires a separate search.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, there is no generic and reasons for distinctiveness of anti IL-21 receptor antibody are not advances over prior art.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

If Invention II is elected, a further election of species is required:

This application contains claim 14 from Invention II directed to the following patentably distinct species: an isolated antibody expressed by a host cell having ATCC deposit designation No. PTA-5030 or PTA 5031. The species are independent or distinct because they are products of a different cell lines and require a separate search.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, there is no generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims

readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

If applicant elects Invention III, a further election of species is required:

This application contains claim 26 from Invention III directed to the following patentably distinct species: methods of regulating an immune response in a T cell, B cell, NK cell, macrophage or a synovial cell. The species are independent or distinct because they represent different cell types, each cell type requiring separate searches and consideration of the art.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, there is no generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim

is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

If the applicant elects Invention IV, a further election of species is required:

This application contains claims 29-31 from Invention IV directed to the following patentably distinct species: multiple sclerosis, rheumatoid arthritis, systemic lupus erythematosus, juvenile rheumatoid arthritis, osteoarthritis, psoriatic arthritis, ankylosing spondylitis, transplant rejection, inflammatory bowel disease and Crohn's disease. The species are independent or distinct because they refer to distinct disorders, each disorder requiring separate search and consideration of the art.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, any immune cell-associated disorder is generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim

is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Notice of possible rejoinder

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between

product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elly-Gerald Stoica whose telephone number is (571) 272-9941. The examiner can normally be reached on 8:30-17:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda G. Brumback can be reached on (571) 272-0961. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Lorraine Spector

LORRAINE SPECTOR
PRIMARY EXAMINER